REMARKS

Applicant has amended the specification and claims to more particularly define the invention taking into consideration the Examiner's answer which is believed to contain a new ground of rejection with respect to newly added prior art and rather than petition this issue, an RCE has been filed along with the present amendment to the specification and claims.

The specification has been amended to emphasize that the invention concerns the film for packaging pharmaceutical and/or cosmetic products which are liquids and which contain aggressive components, such as polar components, non polar components, ions, salts, oils, surface active components, antimicrobial components, macromolecules and the like, see for example page 1 of the specification. The various components which the presently claimed film is useful in containing are aggressive components as set forth on page 4 of the specification. This amendment to the specification does not introduce new matter as would be appreciated by one of ordinary skill in the art to which the invention pertains.

The specification has been further amended to clarify that the polymeric materials are homopolymeric materials as by the term homopolymer is a polymer which is built up of a chain of identical molecules as noted on page 6 of the specification.

Clearly, the specific polymers such as polyethylene, polypropolyene and the like are homopolymers as would be appreciated by one of ordinary skill in the art. Therefore, the use of this term in the specification and claims does not introduce new matter as would be appreciated by one of ordinary skill in the art. Moreover, the amended specification and claims fully comply with the written description requirement of 35 U.S.C. 112, first paragraph; as the specification and original claims would be interpreted by one of ordinary skill in the art to which the invention pertains.

Moreover, the amendments to the specification and claims clarifies the issue with respect to what is submitted by Applicant to be overly broad interpretation of the previously presented claim language and as argued to be supported by the Alger reference in view of the change to the interpretation, at least as now understood by

Application, of the reference relied upon in the rejection. Clearly, the present amended claims are not anticipated over the new rejection of claims 1-6 and 13 and 14 in view of JP 63/24944 as interpreted by Alger. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In this regard, Applicant's wish to emphasize that the use of the term "polyolefin" in the present specification was in terms in the meaning of "homopolymer polyolefin" as supported by the specification as originally filed, on page 6, lines 21-24. The use of the term homopolymeric polyolefin in the claims and in the specification is to avoid confusion with heteropolymeric polyolefins that contain derivatives such as ethylacrylate or maleic anhydride or vinylacetate. The advantage of such a homopolymeric polyolefin as used presently claimed invention is that it satisfies the regulation for use in contact with pharmaceuticals, ophthalmic and cosmetic preparations in accordance with packaging requirements for such products for human use or consumption. Other polyolefins that contain acrylic acid groups, or maleic anhydride groups, or vinylacetate groups, or rubber substances do not satisfy these requirements.

The presently claimed invention allows the use of homopolymeric polyolefins by allowing these homopolymeric polyolefins to be attached to the PCTFE layer, through an intermediary jointing layer which makes the resulting layer package suitable for packaging liquids that contain aggressive substances (e.g. phenol or metacresol or benzylalcohol or peroxides) that occur in pharmaceutical, cosmetic and other liquid products. These aggressive substances can, if they could cross the barrier layer, loosen the layers underneath and make the package unsuitable for use.

Claim 1 is amended now specifies the adhesive layer is composed of a copolymer of ethylene and glycidyl methacrylate (EGMA) between the thermoplastic layer and the fluoro polymer. The discovery of the special characteristics of ethylene-glycidyl methacrylate copolymers as bonding agents and intermediate jointing layers of PCTFE and other hard-to-bind materials to other layers, was described in an application filed on December 18, 2003 by the present Applicant, and a PCT document (PCT/BE03/000226) which forms the basis of the present U.S. application.

These special characteristics have more recently been scientifically corroborated and documented by a PhD thesis of Mr. Kahlid Lamnawar, entitled "Rheolgie aux interfaces des Materiaux polymeres multicouches et role de l'interphase dans les ecoulements stratifies en co-extrusion," and presented on September 24, 2007 at the Institut National des Sciences Appliquees de Lyon, France, p 68 and 73, section 2. Applicants enclose and submit herewith a translation of the key points for consideration.

Dr. Lamnawar demonstrates by means of Differential Scanning Calorimetry measurements that a polyethylene grafted with glycidyl-methacrylate to the extent of 8% of the mass, and identical to the one used in the jointing layer by the Applicant, exhibits an unexpected high fluidity and reactivity, under similar or identical processing conditions as disclosed by the Applicant, features that have advantageously been used in the invention for difficult-to-bind adjacent film layers, in case a homopolymeric polyolefin and a polychlorotetrafluorethylene (PCTFE).

One advantage of this jointing layer of the present invention is that it allows the elimination of the rubber fraction such as the styrene-ethylene-butylene-styrene block copolmyer in the adhesive layer mandatorily present in Tsai, thereby reducing the likelihood of migration of aggressive substances through this layer.

Another advantage of the jointing layer in the present invention is that it allows the outer layer in contact with the packed liquid to consist of a homopolymeric polyolefin, which is not only capable of preventing migration of aggressive chemicals in the packaging material, but which also conforms to regulations on packaging material for pharmaceuticals, cosmetics, and food. Aggressive chemicals are substances such as phenol, metacresol, benzylalcohol, peroxides and others.

Applicants have carefully considered the rejection of claims 7-12 as being unpatentable on the grounds of obviousness over the teachings of Tsai in view of Annegret but is most respectfully traversed based on the following. Applicant most respectfully submits that the method to produce the multilayered film presently claimed, the following can be said. The preferred method for making the multilayered structure is to co-extrude the outer homopolymeric polyolefin layer and the glycidyl containing

jointing layer first, and to laminate the PCTFE layer onto this package later on. In this way, the polyolefin and the jointing layer can interact at the right temperature, to obtain a good bond between them.

This is confirmed by the thesis of Dr. Lamnawar in which the jointing of polyethylene with Lotader, a copolymer of ethylene and glycidyl-methacrylate has been studied. The following quote is from the thesis (Lotader is a polyethylene grafted with glycidyl-methacrylate):

"The fusion range of Latader extends from 96°C to 110°C, but is centered around 106°C. We draw the attention to the change of the base line, in an exothermic way, in the first run towards 250°C. This change disappears in the course of the later run: it is possibly an indication of the start of the cross linking of Lotader."

This is why the jointing of the polyethylene outer layer and the jointing layer is carried out in a separate co-extrusion step, wherein the right temperature at the interface between both layers is reached for the bonding to occur.

The PCTFE layer can be added in a subsequent lamination step. Annegret does not use a coextrusion step but does use lamination steps.

Tsai joins a polyolefin layer to a PCTFE layer by means of a jointing layer containing acrylic acid or acrylates, and a rubber block copolymer. Tsai does not specify the method how to produce such a material, but teaches that the multilayer film may be prepared in any conventional manner.

In an effort to further distinguish over the prior art, Applicant replaces the appealed claims 12-17 of the application by the following single amended method independent claim:

7. Method for manufacturing a film according to claim 1, comprising a coextrusion step of the homopolymeric polyolefin outer layer and the glycidyl methacrylate containing jointing layer, followed by a lamination step whereby the polychlorofluorethylene (PCTFE) layer is joined to the jointing layer.

A basis for this amendment is found in claim 8, which has been canceled without prejudice or disclaimer. Also, the amendment is supported by Figure 2. The presently

claimed method defines the best combination of existing production techniques to obtain the product defined in claim 1. The scientific reasons to support this method which comprises the coextrusion of the homopolymeric polyolefin layer and the glycidyl containing jointing layer first to let them fuse at the right temperature, followed by a lamination step to add the PCTFE layer, are also explained above.

Applicants have carefully considered the rejection of claims 1-6, 13 and 14 over Susumu but is most respectfully traversed based on the following and the reasons already of record which are herein incorporated by reference.

Applicant most respectfully submits that since the claims in this application have all been limited to "homopolymeric" polyolefin layers, the ethylene-ethylacrylate-maleic anhydride terpolymer specified in the first claim of Susumu is no longer relevant to this application. The Examiner does not accept the preamble language of "for packaging liquid products" since it is not essential to understanding limitations or terms in the body of the claim but this term clearly limits the claims as it breathes life into the claims.

Nevertheless, Applicant has replaced "for packaging liquid products" by "for packaging liquid products as pharmaceuticals and cosmetics that contain aggressive substances" in claim 1 as discussed above.

It is indeed the purpose of the present invention to be able to present a homopolymeric polyolefin as an inert barrier layer in contact with the content of the package, that is capable of meeting the regulations for packaging materials in contact with pharmaceuticals, cosmetics or other liquid products that contain aggressive substances, while still allowing this outer layer to be joined to a PCTFE layer by means of a jointing layer. Accordingly, the rejection should be withdrawn.

Applicants have carefully considered the rejection of claims 1-4 over Tsai but it is most respectfully traversed based on the following.

The Examiner noted that the jointing layer of claims 1-4 of the present application was not limited to any particular material and did not exclude any particular material, such as presented by Tsai.

This is no longer so as the jointing layer in claim 1, wherein the jointing layer is

now specified as consisting of a copolymer of ethylene and glycidyl-methacrylate (EGMA).

Also the intended use of the packaging material of this application has now been better specified in the amended first claim, where it is mentioned that the film is for packaging liquid products such as pharmaceuticals and cosmetics that contain aggressive substances. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the specification and claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,
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Thèse

Rhéologie aux interfaces des matériaux polymères multicouches et rôle de l'interphase dans les écoulements stratifiés en coextrusion

Présentée devant
L'institut National des Sciences Appliquées de Lyon

Pour obtenir
Le grade de docteur

École doctorale : Matériaux de Lyon
Spécialité : Matériaux Polymères et Composites

Par
Khalid Lamnawar

Soutenue le 24 Septembre 2007 à
l'INSA de Lyon
Jury MM.

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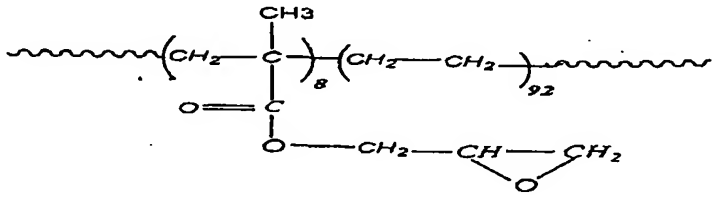
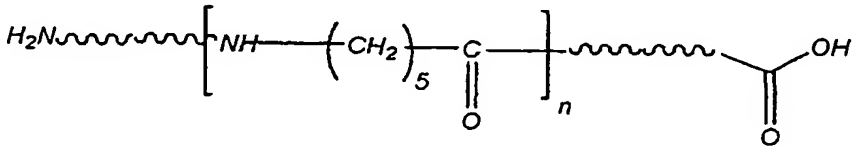
C'est un polyéthylène obtenu par voie radicalaire sous haute pression (PELD). Il s'agit d'un grade standard pour l'extrusion des films. Il nous servira de référence non réactive pour l'étude de nos systèmes multicouches PE/PA.

2.2. Le polyéthylène greffé méthacrylate de glycidyle ou liant (Lotader®AX 8840)



Il s'agit d'un copolymère d'éthylène et de glycidyle méthacrylate (PEGMA) présentant une fonction époxyde toutes les 92 liaisons C-C, autrement dit 8% en masse de la fonction GMA. Cette génération de matériau caractérisée par sa réactivité, sa fluidité est utilisée comme liant pour les systèmes multicouches (Macosko et al. [2002]). Une autre gamme de Lotader constituée de terpolymères statistiques fonctionnalisés anhydride maléique, acrylate d'éthyle, a été étudiée par Montanari et al. [1992] pour constituer la phase élastomère d'un mélange TPE avec une phase matrice du PA12.

2.3. Les polyamide 6 (Capron ® : PA6 (1) et Ultramid BN40 : PA6 (2))



Ils se présentent sous formes de granulés et sont obtenus par un processus de polymérisation anionique d'un caprolactame. Un lactamate est produit en solution, en présence d'un amorceur NaH. Il peut ensuite réagir avec le caprolactame conduisant à la formation du polyamide 6 qui, insoluble dans le solvant, précipite :

PE-GMA

La plage de fusion du Lotader s'étend de 96°C à 110°C. Elle est centrée sur 106°C. Nous remarquons un changement de ligne de base, dans un sens exothermique, pour la première montée (trait vert) vers les 250 °C. Ce changement disparaît au cours des autres montées : C'est peut être un indice du début d'auto-réticulation du Lotader AX8840.

La Figure 31 et le Tableau 4 présentent les résultats obtenus pour une même rampe de 10 °C/min en montée et en descente :

Etat de la matière	**Tg (°C)**	**T_{fus} Pic (°C)**	**T_{fus} Onset (°C)**	**ΔH_{fus} (J/g)**	**Cristallinité X_c (%)**
Granulométrie (5 mm) ρ=0.94g/cm³	Basses températures T<-50°C, difficile à déterminer.	106.4	92.2	75.5	53.7

Tableau 4 : Résultats de la DSC obtenus pour le Lotader avec V_m=V_c=10 °C/min

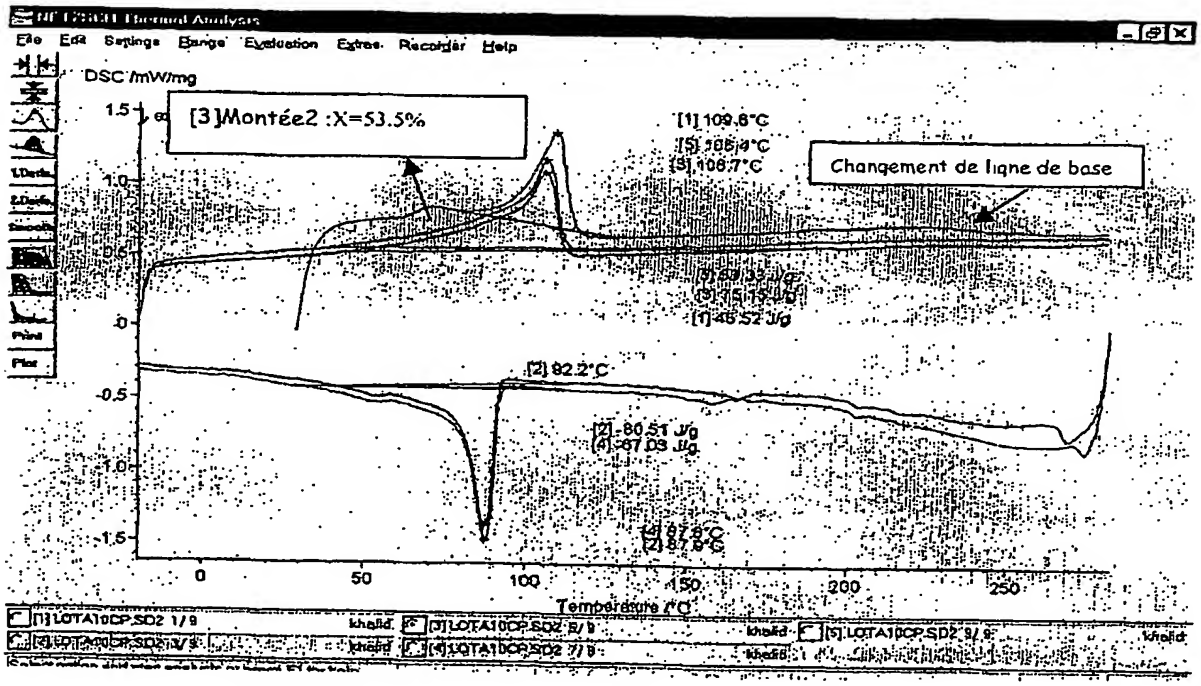


Figure 31 : Courbes DSC du Lotader à V_m=V_c=10°C/min

Translation of enclosure 2, the key points:

2.2 polyethylene grafted with glycidyl methacrylate or the bonding agent (Lotader AX 8840)

it is about a copolymer of ethylene and glycidyl methacrymate (PGEMA) having an epoxide function every 92 C-C bonds, in other words 8% of the mass of the function glycidyl methacrylate.

This generation of materials is characterised by its reactivity, its fluidity, and is used as a binding agent for multilayer systems.

comments: those extraordinary characteristics and capabilities of these kind of materials and a way to manufacture multilayer barriers with them has been discovered indeed by the applicant already in 2003 (priority date of the patent application), and has now been corroborated independently by university studies only published in 2007.

PE-GMA:

the fusion range of Lotader extends from 96°C to 110°C, but is centred around 106°C.

We draw the attention to the change of the base line, in an exothermic way, in the first run towards 250°C.

This change disappears in the course of the later runs : it is possibly an indication of the start of self cross linking of the Lotader AX8840.

comments: it is exactly this reactivity over the same temperature range as used by the applicant in its inventive method to make multilayer barrier films with PCTFE that was discovered already years ago by the applicant (in 2003) before the publication of this study (in 2007).